

THOMAS L. GARTHWAITE, M.D. Director and Chief Medical Officer

FRED LEAF
Chief Operating Officer

COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES 313 N. Figueroa, Los Angeles, CA 90012 (213) 240-8101

November 18, 2004

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

BOARD OF SUPERVISORS

Gloria Molina First District

Yvonne Brathwaite Burke Second District

> Zev Yaroslavsky Third District

Don Knabe Fourth District

Michael D. Antonovich Fifth District

### TWO NOTICE OF COOPERATIVE AGREEMENTS FOR THE INTERVENTION EPIDEMIOLOGY RESEARCH STUDY OF HIV/AIDS DIRECTLY ADMINISTERED ANTIRETROVIRAL THERAPY STUDY

(All Districts) (3 Votes)

#### IT IS RECOMMENDED THAT THE BOARD:

- 1. Approve and instruct the Director of Health Services, or his designee, to accept Amendment No. 1 to Notice of Cooperative Agreement (NCA) No. U64/CCU919440-04, Exhibit I, from the Federal Centers for Disease Control and Prevention (CDC) for the Intervention Epidemiology Research Study of HIV/AIDS Directly Administered Antiretroviral Therapy (HIV/AIDS DAART) providing for the carryover of \$50,038 in unobligated funds from the project budget period of September 30, 2002 through September 29, 2003 to the project budget period of September 30, 2003 through September 29, 2004, increasing the total maximum obligation from \$388,126 to \$438,164.
- Approve and instruct the Director of Health Services, or his designee, to accept NCA No. U64/CCU919440-05, Exhibit II, from the CDC to support the HIV/AIDS DAART study in the amount of \$213,056 for the project budget period commencing on September 30, 2004 through September 29, 2005.
- 3. Delegate authority to the Director of Health Services, or his designee, to accept and sign amendments to NCA No. U64/CCU919440-05, which do not exceed 30% of the base award, upon review and approval by County Counsel, followed by notification of the Board offices.

The Honorable Board of Supervisors November 18, 2004 Page 2

#### PURPOSE AND JUSTIFICATION OF RECOMMENDED ACTIONS:

Board approval of unobligated carryover funds will allow the Department of Health Services to utilize unspent grant monies from the prior project budget periods. Acceptance of NCA No. U64/CCU919440-05 will provide new funding support for continued research for HIV-infected persons with the goal of improving the disease course.

#### FISCAL IMPACT/FINANCING:

The total program cost for the project budget period of September 30, 2003 through September 29, 2004 is \$438,164, 100% offset by CDC funds with no net County costs.

The total program cost for the project period period of September 30, 2004 through September 29, 2005 is \$213,056, 100% offset by CDC funds with no net County costs.

Funding for this program has been included in the Fiscal Year (FY) 2004-05 Board Adopted Budget and will be requested in subsequent years.

#### FACTS AND PROVISIONS/ LEGAL REQUIREMENTS:

On March 13, 2001, the Board approved NCA No. U64/CCU919440 from the CDC for HIV/AIDS DAART for the period of September 30, 2000 through September 29, 2001 in the amount of \$196,583 to conduct a five year research study on HIV-infected persons.

On January 29, 2002, the Board approved NCA No. U64/CCU919440-02 and Amendment No. 1 to U64/CCU919440-02 from the CDC for the project budget period of September 30, 2001 through September 29, 2002, in the amount of \$353,665 and \$38,991, respectively, for a total of \$392,656.

On December 3, 2002, the Board approved NCA No. U64/CCU919440-03 from the CDC for the project budget period of September 30, 2002 through September 29, 2003 in the amount of \$396,585, and delegated authority to the Director, or his designee to accept subsequent funding and amendments to the NCA, not to exceed 25% of the base award.

On December 3, 2003, the Department exercised the delegated authorized by the Board on December 3, 2002, to accept NCA No. U64/CCU919440-04 in the amount of \$388,126 from the CDC for the project budget period of September 30, 2003 through September 29, 2004 for continuation of the DAART study.

County Counsel has reviewed the attached NCAs (Exhibits I and II) as to form.

Attachment A provides additional information. Attachment B is the Grant Management Statement for grant awards exceeding \$100,000.

The Honorable Board of Supervisors November 18, 2004 Page 3

#### **CONTRACTING PROCESS:**

Not applicable.

### IMPACT ON CURRENT SERVICES (OR PROJECTS):

The impact of this research study on HIV- infected persons will not be known until the study is completed.

The recommended amendment and funding for Year 5 will continue the provision of funding support for continued research of HIV-infected persons through September 29, 2005.

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,

Thomas L. Garthwaite, M.D.

Director and Chief Medical Officer

Attachments (3)

cc: Chief Administrative Officer

County Counsel

Executive Officer, Board of Supervisors

BLETCD3544.rdt

#### SUMMARY OF AGREEMENT

#### 1. TYPE OF SERVICES:

Research of HIV-infected persons to improve the disease course, and to evaluate the efficacy and feasibility of three adherence models for the HIV/AIDS Directly Administered Antiretroviral Therapy (DAART) study.

#### 2. AGENCY/CONTACT PERSON:

Centers for Disease Control and Prevention (CDC) Procurement and Grants Office 2920 Brandywine Road, Room 3000, Mail Stop E-15 Atlanta, GA 30341 - 5539

Contact: Roslyn Curington, Grants Manager Specialist Telephone: (770) 488-2767 Facsimile: (770) 488-2670

e-mail address: rcurington@cdc.gov

#### 3. TERM:

The term of the NCA No. U64/CCU919440-04-1 is September 30, 2003 through September 29, 2004.

The term of the NCA No. U64/CCU919440-05 is September 30, 2004 through September 29, 2005.

#### 4. FINANCIAL INFORMATION:

The total program cost for the project budget period of September 30, 2003 through September 29, 2004 is \$438,164, 100% offset by CDC funds with no net County costs.

The total program cost for the project budget period of September 30, 2004 through September 29, 2005 is \$213,056, 100% offset by CDC funds with no net County costs.

Funding for this program has been included in the Fiscal Year (FY) 2004-05 Board Adopted Budget.

#### 5. GEOGRAPHIC AREA SERVED:

Countywide.

#### 6. DESIGNATED ACCOUNTABLE FOR MONITORING AND EVALUATIONS:

Gordon Bunch, Director, HIV Epidemiology Program

#### 7. APPROVALS:

Public Health: John F. Schunhoff, Ph.D., Chief of Operations

Contract Administration: Irene E. Riley, Director

County Counsel (as to form): Kelly Auerbach-Hassel, Deputy County Counsel

# ATTACHMENT B

# Los Angeles County Chief Administrative Office Grant Management Statement for Grants Exceeding \$100,000

Department: Health S	Services							
Г								
Grant Project Title and Do		·						
HTV Epidemilogy Prog	gram - Directly Administ	ered Antiretroviral Thera	py (DAART)					
Funding Agency	Funding Agency Program (Fed. Grant #/State Bill or Code #) Grant Acceptance Deadline							
Federal - CDC	Acceptance of Allocation	on Agreement No. U64/C	CU919440-05	ASAP				
Total Amount of Grant Fu	anding: \$213,056	Coun	ty Match Requi	rements	· · · · · · · · · · · · · · · · · · ·			
1						mber	29, 2005	
Number of Personnel Hire	ed Under this Grant:		Full Time	3	Part ?	Γime		
	Obligations Imposed	d on the County When t	he Grant Expi	res				
Will all personnel hired fo	or this program be inform	ed this is a grant funded	program?	Yes	X	No		
Will all personnel hired fo	r this program be placed	on temporary ("N") item	ıs?	Yes	X	No		
Is the County obligated to	continue this program af	fter the grant expires		Yes		No	X	
If the County is not obliga	ted to continue this progr	ram after the grant expire	s, the Departme	nt will:				
a). Absorb the program co	ost without reducing other	er services		Yes	***************************************	No	X	
b). Identify other revenue	sources			Yes		No	X	
(Describe)								
c). Eliminate or reduce, as	s appropriate, positions/p	program costs funded by t	his grant.	Yes	X	No		
Impact of additional person	nnel on existing space:	Not applicable.						
Other requirements not me	entioned above Not	applicable.						
Department Head Signatur	e AMUSI VIII			Dat	e [[	(5/0	<i>f</i>	

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. SUPERSEDES AWARD NOTICE DATED	73.741				PUBLI	C HEALTH SE	RVICE	
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. GRANT NO.	5. ADMINISTRATIVE CODES	***************************************		AUTHOR	IZATIO	N (LEGISLAT	ION/REGULA	CNOIT
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· BUDGET PERIOD 09/30/2003 ROM	09/29/2004 Through	í		AHK	1 2 20	004		
. TITLE OF PROJECT (OR PROGRAM)				I HWEP	IDEMIO	_0GY		
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. GRANTEE NAME AND ADDRESS	EDT OF HEALTH ON			DIRECTOR OF PR			PRINCIPAL INV	ESTIGATOR)
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LOS ANGELES, CA 9001				S ANGELES			30112	1720
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PHS GRANT FUNDS ONLY		Α.	AMOUNT	OF PHS FINANCIAL ASS	SISTANCE (	FROM 11.00	. \$	438,164
TOTAL PROJECT COSTS INCLUDING GRANT FUNDS PARTICIPATION	AND ALL OTHER FINANCIAL	В.	LESS UN	OBLIGATED BALANCE FE	ROM PRIOR	BUDGET PERIODS.	. \$	50,038
(PLACE NUMERAL ON LINE)	NAME AND ADDRESS OF THE PARTY O	с.	LESS CU	MULATIVE PRIOR AWARI	SIHT (2)	BUDGET PERIOD	. \$	388,126
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TOTAL APPROVED BUDGET				SEE REMARKS)				
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18. CRS.EIN: 1-956000927-A1 | 19. LIST NO.:

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ADMINISTRATIVE CODE

DOCUMENT NO.

FY-CAN

CN-078-A04

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NOTICE OF COOPERATIVE AGREEMENT	PAGE 2 OF <b>2</b>	DATE ISSUED
AWARD (Continuation Sheet)	AWARD NO.	U64/CCU919440-4-1

### TERMS AND CONDITIONS OF AWARD

# NOTE 1: <u>CARRYOVER REQUEST</u>

The purpose of this amendment Notice of Award is to provide carryover of unobligated funds of \$50,038.00 from budget period 3 to current budget period, as requested in the letter dated February 04, 2004. This amount will be subject to reduction if the actual unobligated balance is less.

		Amount of	
	Amount	Carry-over	Revised
<b>Budget Categories</b>	<u>Awarded</u>	<b>Funding</b>	<u>Amount</u>
Salaries & Wages	\$200,148	\$24,864	\$225,012
	•	• • •	
Fringe Benefits	53,410	8,876	62,286
Equipment	0	7,258	7,258
Supplies	0	0	0
Contractual	, <b>0</b>	0	0
Travel	0	1,757	1,757
Other	56,195	0	56,195
Consultant	19,742	0	19,742
<b>Total Direct</b>	\$329,495	\$42,755	\$372,250
<b>Indirect Costs</b>	58,631	7,283	65,914
<b>Total Costs</b>	\$388,126	\$50,038	\$438,164

#### NOTE 2:

All other terms and conditions remains the same.

# LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM DIRECTLY ADMINISTERED ANTIRETROVIRAL THERAPY (DAART)

## SEPTEMBER 30, 2003 - SEPTEMBER 29, 2004

	==	Annual Salary	Monthly Salary	# of Pos	% of Time	# of Mos	Total Budget	Chng	Revised Budget
I.	COUNTY PERSONNEL								
••	Chief Epidemiologist								
	Amy Wohl, Ph.D.	\$79,104	\$6,592	1	30%	12	23,731	8,438	32,169
	Research Analyst II	φ, ο, , ο ι	Ψ0,002	•	0070		20,701	0,400	02,100
	Wendy Garland	50,136	4,178	1	80%	12	40,109	2,446	42,555
	Epidemiology Analyst	00,.00	.,.,.	•	0070		70,100	2.,	72,000
	Rosa Valencia	49,152	4,096	1	100%	12	49,152	0	49,152
	Community Workers	70,702	1,000	•	.00,0	. —	.0,.02	v	10,102
	Anna Ballesteros	29,052	2,421	1	100%	12	29,052	0	29,052
	Otilia Galindo	29,052	2,421	1	100%	12	29,052	0	29,052
	Benjamin Iniguez	29,052	2,421	1	100%	12	29,052	0	29,052
	Administrative Aid	_0,00_	,	,	.0075		20,002		20,002
	Susan Cheng, MPH	\$30,502	2542	1	100%	5.5	0	13,980	13,980
	Total Salaries				5.10		200,148	24,864	225,012
	Employee Benefits @ 35.69				0.10		40,337	8,876	49,214
	Employee Benefits @ 15%						13,073	0,070	13,073
	Total Personnel						253,558	33,740	287,299
11.	OPERATING EXPENSES								
	Cellular Phones						2,400	0	2,400
	Office Supplies						250	0	250
	Equipment						0	7,258	7,258
	Travel						500	1,757	2,257
	Pharmacy						50	0	50
	Mileage/Parking						19,380	0	19,380
	Space						15,840	0	15,840
	Participant Incentives						14,175	0	14,175
	Laboratory Costs						3,600	0	3,600
	Sole Source Purchase Orde	ers:							
	Kathleen Squires						5,034	0	5,034
	Andrea Kovacs						9,079	0	9,079
	Mallory Witt						5,629	0	5,629
	Total Subcontracts						19,742	0	19,742
	Total Operating Expenses						75,937	9,015	84,952
IV.	Indirect Cost (29.2934% o						58,631	7,283	65,914
٧.	TOTAL BUDGET s:grants/cdcpro03/DAART/DA	ART2003 2	.004				\$388,126	50,038	\$438,164

# COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM

Intervention Epidemiologic Research Study on HIV/AIDS (DAART)
Cooperative Agreement No. U62/CCU919440: Carryover of 2002/2003 Funds
September 30, 2003 - September 29, 2004

1.	COUNTY PERSONNEL	Annual Salary	Monthly Salary	# of Positions	% of Time	# of Mos.	Total
	Principal Investigator Amy Wohl, Ph.D.	\$79,104	\$6,592	1	32%	4	\$8,438
	Research Analyst II Wendy Garland, MPH	48,912	4,076	1	10%	6	2,446
	Administrative Aid Susan Cheng, MPH	\$30,502	\$2,542	1	100%	5.5	13,980
	Total Salaries						24,864
	Employee Benefits @35.6991% Total Salaries & EB						8,876 <b>33,740</b>
II.	Operating Expenses:						
	Equipment Travel						7,258 1,757
	Subtotal Operating						9,015
	Total Operating Expenses						9,015
111.	Indirect Cost @ 29.2934%						7,283
IV.	Total Budget						\$50,038

# LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM DIRECTLY ADMINISTERED ANTIRETROVIRAL THERAPY (DAART)

#### SEPTEMBER 30, 2003 - SEPTEMBER 29, 2004

	=	Annual Salary	Monthly	# of Pos	% of Time	# of Mos	Total Budget
١.	COUNTY PERSONNEL						
	Chief Epidemiologist						
	Amy Wohl, Ph.D.	\$79,104	\$6,592	1	30%	12	23,731
	Research Analyst II						
	Wendy Garland	50,136	4,178	1	80%	12	40,109
	Epidemiology Analyst						
	Rosa Valencia	49,152	4,096	1	100%	12	49,152
	Community Workers						
	Anna Ballesteros	29,052	2,421	1	100%	12	29,052
	Otilia Galindo	29,052	2,421	1	100%	12	29,052
	Benjamin Iniguez	29,052	2,421	1	100%	12	29,052
	Total Salaries				5.10		200,148
	Employee Benefits @ 35.6991%						40,337
	Employee Benefits @ 15%						13,073
	Total Personnel						253,558
II.	OPERATING EXPENSES						
	Cellular Phones						2,400
	Office Supplies						250
	Travel						500
	Pharmacy						50
	Mileage/Parking						19,380
	Space						15,840
	Participant Incentives						14,175
	Laboratory Costs						3,600
	Sole Source Purchase Orders:						
	Kathleen Squires						5,034
	Andrea Kovacs						9,079
	Mallory Witt						5,629
	Total Subcontracts						19,742
	Total Operating Expenses						75,937
IV.	Indirect Cost (29.2934% of total salarie						58,631
٧.	TOTAL BUDGET						\$388,126



#### PROJECT OFFICER / PROJECT CONSULTANT

# SEMI-ANNUAL GRANTEE PROGRESS REPORT EVALUATION or TECHNICAL REVIEW

Date: 8/15/2003

Grantee Name: Amy Rock Wohl, Ph.D., County of Los Angeles Department of Health Services

Award Number: U64/CCU919440

Program Announcement Number: 00006

Amount Requested: \$388,126

Amount Recommended/Funded: \$388,126

Name of Evaluator / Reviewer (print): Paul J. Weidle, Pharm.D., MPH

Signature / and Julie That DAPLY

Compliance with Content Review Guidelines: Yes (date) 7/19/2003; No

Progress in Program or Study Objectives or Activities: Describe (by indicating its strengths and weaknesses) the current state of the program or study.

Title of Study: A Clinic-based Evaluation of Three Adherence Models for HAART - Directly Administered Antiretroviral Therapy (DAART), Intensive Adherence Support and Standard Care.

We are completing year three of this four year study. As of July 14, 2003, 180 patients have been enrolled into the study: 104 patients completed at least six months and 48 patients have completed 12 months. 51 patients are currently enrolled in one of the six month interventions. 8 patients have been lost to follow-up and 13 patients exited the study early.

The study randomizes patients who are antiretroviral naïve or treatment-experienced, but have failed no more that one prior antiretroviral regimen to: 1) DAART -- community-worker visit once per day/5 days per week to observe ingestion of one dose and administer a prepackaged supply for the subsequent dose, 2) Intensive Adherence Program (IAP) - case management by weekly contact with patient to address adherence as well as social/financial issues, 3) Standard of Care (SOC). Patients stay in the assigned arm for six months then step-down to the next level of intensity. Patients will be followed for up to 24 months. The primary bio-medical outcome is viral load < 400 copies/ml at six months - chosen to provide a clinically meaningful measure of these behavioral and social interventions. Multiple secondary analyses are planned including effects on adherence to ARVs, use of case management services, and health-care utilization.

A Data Monitoring committee (DMC) was established in January 2003 to review



study progress and procedures. The committee consists of three members, two physicians and a biostatistician. All members are independent from the study. Formal reports will be submitted to the DMC when 150 patients have completed six months in the study and at study completion. An informal report with baseline demographics and aggregate viral load data has been prepared at the request of the DMC for review in July 2003.

A Community Advisory Board (CAB) has been assembled and last met in December 2002. CAB members include individuals involved in HIV/AIDS and adherence research, case management services, treatment advocacy, related pharmaceuticals, and medical services as well as recipients of these services. Meeting topics have included intervention and recruitment procedures, recruitment challenges, and staff training/education.

Several abstracts have been presented:

- 1. Harwood M, Wohl A, Garland W, Valencia R. Improving Patient Treatment Adherence Using an Intensive Case Management Model. The United States Conference on AIDS, September 2002, Anaheim, California.
- 2. Wohl A, Garland W, Witt M, Larsen R, Squires K, Hader S, Weidle P. A randomized trial of the impact of a community-based directly administered antiretroviral therapy (DAART) program, an intensive adherence support program (IAP), and standard of care (SOC) on HAART adherence. Elements of Success: An International Conference on Adherence to Antiretroviral Therapy, December 2002, Dallas, Texas.
- 3. Harwood M, Wohl A, Garland W, Lu S, Witt M, Larsen R, Squires K. Using an Intensive Case Management Model to Overcome Obstacles to HAART Adherence. Elements of Success: An International Conference on Adherence to Antiretroviral Therapy, December 2002, Dallas, Texas.
- 4. Wohl A, Garland W, Larsen R, Squires K, Kovacs A, Witt M, Weidle P, Hader S. A Clinic-Based Evaluation of Three Adherence Models for HAART. Presented at a Working Group on the Use of Directly Observed Therapy and Other Community Based Efforts to Get HAART to Those Who Aren't Getting It, February 2003, Boston, Massachussetts.
- 5. Wohl A, Garland W, Larsen R, Squires K, Kovacs A, Witt M, Weidle P, Hader S. Early Experience from a Community-Based Directly Administered Therapy (DAART) Program in a Large Urban Setting. Submitted to Clinical Infectious Diseases June 2003.

Proposed Changes/Modifications in Objectives or Program Plan: Describe the proposed changes in objectives or plans and the grantee's ability to achieve them.

During year four of this project, the primary activity will be to enroll the anticipated grand total of 300 persons by the end of March 2004. All of which will have completed at least six months in the study by the end of September



2004.

Second, data cleaning, editing and analysis will be conducted. A preliminary analysis of risk behaviors will be conducted and will focus on changes in substance use and sexual risk behaviors over time. Also, data from the Providers Survey will be analyzed to assess changes in adherence support in standard care at the study sites and over time.

CDC-Atlanta will take the lead in developing a plan for completion of an analysis that will assess Health care utilization and quantification of health care resource allocation/cost. The approach for this will be similar to that being done at the DAART study site in Baltimore. The focus of the analysis will include (1) the cost of administering the DAART and Intensive Adherence Program (IAP) services, (2) the utilization of health care services - clinic visits, ER visits, home health care services, antiretroviral drug use, and hospitalizations.

Third, presentations will be made locally to the site's Community Advisory board (CAB) meetings (a minimum of two will be held in 2003-2004), the Los Angeles County Commission on HIV Health Services, and other HIV/AIDs organizations in the Los Angeles area.

We are confident that the grantee will meet all these objectives.

Budget Issues: Describe any budget concerns (yours or grantees) that may affect the study or program plan.

None at this time.

Recommendation: Provide recommendations for improving the objectives, methodology, activities, and other aspects of the study or program.

This study is among the first to critically examine the use of DAART, IAP, and Standard of Care in a clinic-based environment. The site will provide useful data on the effect and costs of a DAART and an IAP program.

We expect to conduct the analysis of the primary analyses in the fall of 2004 after all patients have completed six months of the intervention. During this next year we will make a concerted effort to complete the cost analysis to determine the cost of administering DAART and IAP. We will also quantify health care utilization. Other analyses will be conducted over the next year and we are making plans to present and publish as much as is reasonable. The results of this study will be useful in the near term to LA County, but also have implications for more wide scale implementation should the intervention arms prove to provide a biomedical and/or cost benefit.

# COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM

Intervention Epidemiologic Research Study on HIV/AIDS (DAART)
Cooperative Agreement No. U62/CCU919440
September 30, 2003 - September 29, 2004

1.	COUNTY PERSONNEL	Annual Salary	Monthly Salary	# of Positions	% of Time	# of Mos.	Total
	Principal Investigator Amy Wohl, Ph.D.	\$79,104	\$6,592	1	30%	12	\$23,731
	Co-Investigator Robert Larson, M.D.		n/a	4	5%	12	In-Kind
	Research Analyst II	50,136	4,178	1	80%	12	40,109
	Wendy Garland, MPH Epidemiology Analyst	49,152	4,096	1	100%	12	49,152
	Rosa Valencia Community Worker Ana Ballesteros Otilia Galindo	29,052	2,421	3	100%	12	87,156
	Benjamin Iniquez Total Salaries						200,148
	Employee Benefits @35.6991% Employee Benefits @15% (Commun Total Salaries & EB	ity Workers)		è			40,337 13,073 253,558
II.	Operating Expenses:						
	Office Supplies Laboratory Costs Cellular Phones Pharmacy Incentives						250 3,600 2,400 50 14,175
	Mileage/Parking Travel/Training						19,380 500
	Space/Rent Subtotal Operating						15,840 56,195
	Consultant Costs Mallory Witt, MD Kathleen Squires, MD			,			5,629 5,034
	Andrea Kovacs, MD						9,079
	Total Consultant Costs						19,742
	Total Operating Expenses						\$75,937
III.	Indirect Cost @ 29.2934%						58,631
IV.	Total Budget						\$388,126
	S/Grants/DAART/DARTBD4Y						

Program Announcement Number: 00006 Page 2 of 7



The purpose of this amendment/modification is as follows:

- 1. To provide year 04 funding in the amount of \$388,126.00 in support of Program Announcement Number 00006.
- 2. With the acceptance and performance of this Cooperative Agreement requirement, the grantee hereby agrees to be bound by the terms and conditions identified herein via Notes and Special Provisions.

#### NOTE 1: PUBLICATION

The grantee is reminded that all written materials, audiovisual materials, pictorials, questionnaires, survey instruments, educational curricula and other relevant program materials must be reviewed and approved by an established program review panel. To meet the requirements for a program review panel, you are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If you form your own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. The names of the review panel members should be listed on the Assurance of Compliance form, CDC 0.1113, which is included in the application kit. If the proposed project involves hosting a conference, submit the program review panel's report stating that all materials, including the proposed conference agenda, have been approved this office at least 60 days prior to the conference. Before funds are used to develop educational materials, determine whether suitable materials already exist in the National Prevention Information Network at 1-800-458-5231 or www.cdcnpin.org.

Not complying with these requirements will result in restrictions or disallowance of funds related to the use of unapproved materials. You can obtain a copy of these guidelines from the CDC website at www.cdc.gov/od/pgo/forms/hiv.htm.

Materials that you (or those entities that you support with CDC funds) are currently using that have not received approval must be submitted immediately to your Program Review Panel for clearance. Documentation of the Panel's decision (for approval or disapproval), signed by the Panel chairperson, must be sent to <u>Carlos M. Smiley</u>, Grants Management Officer, at the addressed listed herein.

As you (or those entities that you support with CDC funds) develop or decide to use materials in your program, you must submit them to your Panel for review. Send documentation of the Panel's decision, signed by the Panel chairperson to CDC with your next scheduled progress report (i.e., quarterly narrative).

You are not permitted to reprint any materials that have not been reviewed and approved. Noncompliance with this policy after December 1, 2001, may result your funds for these materials to be restricted or disallowed. Further noncompliance may result in your award being suspended or terminated.

Web page notices must be used on websites to alert individuals who may be searching or browsing the web. The certification of compliance with this requirement must be signed and returned to the Procurement and Grants Office. Not complying with these requirements will result in restrictions or disallowance of funds related to the use of the unapproved materials and related staff activities.

#### NOTE 2: INDIRECT COST

The Los Angeles County Department of Health Services maintains its internally approved indirect cost allocation plan established with Single Audit, dated 12/07/01.

NOTE 3: PRIOR APPROVAL

PROCESS FOR E-MAIL SUBMISSIONS OF PRIOR APPROVALS FOR CDC GRANTS AND

Program Announcement Number: 00006



Page 3 of 7

#### COOPERATIVE AGREEMENTS

With the issuance of this document, the CDC hereby authorizes the use of e-mail submissions of Prior Approvals Request for CDC Cooperative Agreements. However, if electronic submissions are not available to the Grantee, hardcopy submission of the request shall still be accepted.

It is intended that, whenever practical and efficient, all steps in the submission of prior approval requests from grantee institutions and the replies from CDC to such requests be done electronically. This Notice does not represent a change in policy with regard to prior approval requirements contained in the 45CFR Part 92, Subpart C. Subsection 92.30. Rather, it is a change in formal procedure to allow these requests to be submitted and replied to via e-mail. The procedures for submitting such requests are detailed below.

All requests for CDC awarding office prior approval must be made, in writing, to the awarding office Grants Management Officer listed on the Notice of Grant Award no later than 30 days before the proposed change. Failure to obtain prior approval, when required, from the appropriate CDC awarding office may result in the disallowance of costs, termination of an award, or other enforcement action within CDC's authority.

#### Grantee Procedures:

An authorized official of the grantee business office shall initiate the request. It shall include stated coordination with either the principal investigator or program director. It must include the title, institution, telephone number, fax number and e-mail address of both officials. Internal institutional guidelines for the evaluation and approval of the request are the responsibility of the grantee institution. The request, when submitted to CDC, must be transmitted by the authorized institutional official.

When transmitting the request, the authorized institutional official's name, title and institution, telephone number, fax number and e-mail address must be included. It is understood that the transmission of electronic prior approval requests is a clear expression of institutional approval and that all internal procedures have been properly completed. Additionally, the grantee will be responsible for any internal distribution of the request.

The request should include the complete grant number and Program Announcement in the subject line of the e-mail. All information and justification must be included in either plain text in the body of the e-mail request or as an attachment. If unable to transmit the entire request in either of these formats then the request in its entirety must be submitted via "hard-copy."

The requests should be sent to the Grants Management Officer who signs the Notice of Cooperative Agreement; a copy should also be furnished to the Grant Management Specialist and the Program Project Officer.

E-mail addresses for CDC staff can be obtained are enclosed herein. However, please check with the Grant Management Specialist to verify current e-mail addresses.

All requests that require the prior approval of the Grants Management Officer must bear the signatures of an authorized official of the grantee business office as well as that of the principal investigator or program director. Any request received without two signatures will be returned.

Roslyn Curington, Grants Management Specialist Centers for Disease Control and Prevention (CDC) Procurement and Grants Office 2920 Brandywine Road Room 3000 Mail Stop E-15 Atlanta, GA 30341 E-mail: rcurington@cdc.gov

NOTE 4: TECHNICAL REVIEW

Program Announcement Number: 00006



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NOTE 5: DEFERRED COSTS

Items/activities not currently funded, but deferred because of insufficient funds, may be funded within the budget period, should supplemental funds become available.

#### NOTE 6: UNOBLIGATED BALANCE

The amount of \$0.00 unobligated funds from prior budget periods is carried forward for use in this budget period.

Carryover of unobligated funds identified in an Interim Progress Report (Continuation request) or a Financial Status Report (FSR), SF 269, is subject to a reduction in the awarded amount in the event that a final FSR is submitted for an amount less than the previously report amount.

#### NOTE 7: DIRECT ASSISTANCE FUNDS

No direct assistance funds (DA) were awarded.

#### NOTE 8: REPORTING REQUIREMENTS:

PROCESS FOR E-MAIL SUBMISSIONS OF PROGRESS REPORTS AND ANNUAL FINANCIAL STATUS REPORTS FOR CDC COOPERATIVE AGREEMENTS.

With the issuance of this document, the CDC hereby authorizes the use of e-mail submissions of Progress Reports and Annual Financial Status Reports for CDC Cooperative Agreements. However, if electronic submissions are not available to the Grantee, hardcopy submission of the request shall still be accepted.

#### Progress Report and Annual Financial Status Report:

An authorized official of the grantee business office shall initiate the report. It shall include stated coordination with the either the principal investigator or program director. It must include the title, institution, telephone number, fax number and e-mail address of both officials. Internal institutional guidelines for the evaluation and approval of the request are the responsibility of the grantee institution. The request, when submitted to CDC, must be transmitted by the authorized institutional official.

It is understood that with the transmission of electronic reports by the grantee, it is a clear expression of institutional approval and that all internal procedures have been properly completed. Additionally, the grantee will be responsible for any internal distribution of the request.

The request should include the complete grant number and Program Announcement in the subject line of the e-mail. All documentation must be included in either plain text in the body of the e-mail request or as an attachment thereto. If unable to transmit the entire request in either of these formats, then the request in its entirety must be submitted via "hard-copy."

The requests should be sent to the Grants Management Officer who signs the Notice of Cooperative Agreement; a copy should also be furnished to the Grant Management Specialist and the Program Project Officer.

E-mail addresses for CDC staff can be obtained are enclosed herein. However, please check with the Grant Management Specialist to verify current e-mail addresses.

#### CONTENT OF REPORT:

Your progress report shall be submitted on an annual basis.

The <u>progress report</u> must include the following for each program, function, or activity involved:

(1) a description of the program accomplishments and a comparison of actual accomplishments with the

Program Announcement Number: 00006



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objectives established in the work plan for the funding period;

- (2) other pertinent information that includes, but not limited to analysis and explanation of unexpected delays or high costs of performance and a listing of presentations and publications produced by, supported by, or related to program activities; and
- (3) summary of data (subject to approval by the Office of Management and Budget (OMB)).

#### Due Dates:

December 29, 2004

Your financial status report (FSR) must be submitted as follows:

An ANNUAL Financial Status Report (FSR) must be submitted within 90 days after the end of the budget period. This report must be submitted on the Form SF269, and include only those funds authorized and actually expended during the prior year budget period.

A FINAL Progress report is due 90 days after the project period end date. The final report should summarize the entire project. (NOTE: The format for the progress report may be obtained from your project officer).

Either e-mail or Hardcopy submissions shall be directly to:

Carlos M. Smiley, Grants Management Officer Centers for Disease Control and Prevention (CDC) Procurement and Grants Office 2920 Brandywine Road, Room 3000, MS E-15 Atlanta, GA 30341-5539 e-mail address: Csmileyl@cdc.gov ATTN:: Roslyn Curington

Due Date: December 29, 2004.

## NOTE 9: PAYMENT INFORMATION

Payment under this award will be on the direct payment method. At CDC, recipients are placed on one of the two payment methods.

These are Direct Drawdown or Direct, and Manual Drawdown or Manual. It is preferred that Recipients maintain good standing in all fiscal and programmatic areas, thus, maintaining status on a direct drawdown basis, however, under certain conditions, recipients are placed on manual drawdown. For those recipients placed on manual drawdown, the CDC GMO will monitor and control all payment advances for your award. Therefore, PMS 270 forms, as well as correspondence related to payments must be forwarded to the attention of your assigned GMS.

If you are authorized Direct Drawdown, funds will be obtained directly through the Payment Management System (PMS). PMS is administered by the Division of Payment Management, Program Support Center, DHHS. The PMS will forward the following information to you:

- (1) the DHHS Manual for Recipients Financed Under the Payment Management System (PMS)
- (2) the PMS-272 (Status of Federal Cash) forms
- (3) PMS Contact person that is responsible for your account
- (4) Instructions regarding direct deposit and other payment routes.

PMS correspondence, mailed through the U. S. Postal Service, should be addressed as follows:

Division of Payment Management, FMS/PSC/HHS,
P. 0. Box 6021

Rockville, MD 20852.

If a carrier other than the U. S. Postal Service is used, such as United Parcel Service, Federal Express, or other commercial service, the correspondence should be addressed as follows:

Division of Payment Management, FMS/PSC/HHS, Rockwall Building #I, Suite 700, 11400 Rockville Pike,

Program Announcement Number: 00006

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Rockville, MD 20852.



#### CDC CONTACT LIST

#### NOTE 10

#### GRANTS MANAGEMENT SPECIALIST

Roslyn Curington

Centers for Disease Control and Prevention (CDC)

Procurement and Grants Office

2920 Brandywine Road, Room 3000, MS E-15

Atlanta, GA 30341-5539 Telephone: (770) 488-2767 Fax: (770) 488-2670

E-mail address: rcurington@cdc.gov

#### CDC PROJECT OFFICER

Paul Weidle

Project Officer/ Program Consultant

Centers for Disease Control & Prevention (CDC)

Division of HIV/AIDS Prevention Corporate Square, Bldg. 8, MS, E-47

Atlanta, GA 30333 Telephone: (404) 639-6155

Fax: (404) 639-6127 E-Mail: <u>pew6@cdc.gov</u>

#### SPECIAL PROVISIONS

The following provisions are incorporated by reference from Title 45 - Public Welfare, Subtitle DHHS, Part 74 - UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, OTHER NONPROFIT ORGANIZATIONS, AND COMMERCIAL ORGANIZATIONS;

74.1	Purpose and applicability
74.2	Definitions.
74.5	Subawards
74.13	Debarment and suspension
74.14	Special award Conditions
74.17	Certifications and representations
74.21	Standards for financial management systems
74.22	Payment
74,24	Program Income
74.25	Revision of budget and program plans
74.26	Non-Federal audits

Program Announcement Number: 00006

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74.27	Allowable Costs	
74.28	Period of availability of funds	
74.33	Federally owned and exempt property	COPY
74.34	Equipment	
74.35	Supplies	
74.41	Recipient Responsibilities	
74.42	Codes of Conduct	
74.51	Monitoring and Reporting program performance	
74.52	Financial Reporting	•
74.53	Retention and access requirements for records	
74.61	Termination	
74.62	Enforcement	
74.71	Closeout Procedures	
74.73	Collection of amounts due	
74.82	Program Income	

Provisions incorporated by reference have the same force and effect as if they were given in full text. Source: 45 CFR Part 74. Copies of Code of Federal Regulation volumes are available in many libraries and for purchase from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. Copies of OMB Circulars referenced in the provisions may be obtained from the Office of Administration, Publications Unit, Room G-236, New Executive Office Building, Washington, D.C. 20503. An index of existing Circulars is contained in 5 CFR 1310.

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#### PHS-5152-1 (CONTINUED)

DATE ISSUED....: 08/31/2004

GRANT NO.....: U64/CCU919440-05

APPROVAL LIST NO: CO-219-A04

# DIRECT ASSISTANCE BUDGET:

PERSONAL SERVICE:	0
TRAVEL:	0
VACCINE:	0
OTHER SERVICE:	0

NOTICE OF COOPERATIVE AGREEMENT	Page -1-	DATE ISSUED
AWARD (Continuation Sheet)	AWARD NO.	U64/CCU919440-05

### TERMS AND CONDITIONS THIS AWARD

NOTE 1: INCORPORATION: Program Announcement Number <u>00006</u> entitled "Intervention Epidemiologic Research Study of HIV/AIDS DART" and the Interim Progress Report dated July 01, 2004, all applicable regulations and OMB Circulars are made a part of this award by reference.

This continuation award provides funds for budget year 2004, covering the period of September 30, 2004 through September 29, 2005.

#### NOTE 2: INDIRECT COST:

Rate: 21.7971%

Base: Fiscal year 2003 and 2004 countywide cost allocation plan schedule.

#### NOTE 3: REPORTING REQUIREMENTS:

a) Annual Financial Status Report (SF 269 or SF 269A):
The FSR is due to CDC Grants Management Office 90 days after the end of the budget period. Include only those funds authorized and actually expended during the prior year budget period.

Due on: December 29, 2005

b) Final Progress Report:

The final progress report is due 90 days after the project period end date. The final report

should summarize the entire project. (NOTE: The format for the progress report may be obtained from your project officer).

Due on: December 29, 2005

You are hereby authorized to submit your progress report via electronic transmission. If you should choose this method, please submit it to the attention of your Grants Management Specialist. In addition, please furnish a copy of the report to your Project Officer. DO NOT MAIL COPIES. The Specific due dates are as follows:

NOTE 4: HIV PROGRAM REVIEW PANEL REQUIREMENT: The applicant is reminded that all written materials, audiovisual materials, pictorials, questionnaires, survey instruments, websites, educational curricula and other relevant program materials have to be reviewed and approved by an established program review panel. A list of reviewed materials

NOTICE OF COOPERATIVE AGREEMENT	Page - 2 -	DATE ISSUED
AWARD (Continuation Sheet)	AWARD NO.	U65/CCU919440-05

and approval dates must be submitted to the CDC Grants Management Officer.

NOTE 5: CORRESPONDENCE: All correspondence regarding this award must be identified with the award number as shown at the top right of this page.

NOTE 6: PRIOR APPROVAL: "ALL" requests that require the prior approval must bear the signature of an authorized official of the grantee business office as well as that of the principal investigator or program director. Any request received, which reflect only one signature, will be returned to the grantee unprocessed. Additionally, any requests involving funding issues must include a new proposed budget and a narrative justification of the requested changes.

NOTE 7: PUBLICATIONS: Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, such as: This publication (journal article, etc.) was supported by Grant/Cooperative Agreement Number U64/CCU919440-5 from The Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

NOTE 8: EQUIPMENT AND PRODUCTS: To the greatest extent practicable, all equipment and products purchased with CDC funds should be American-made.

NOTE 9: ACKNOWLEDGMENT OF FEDERAL SUPPORT: When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all awardees receiving Federal funds, including and not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

NOTE 10: INSPECTOR GENERAL: For your information, the United States
Department of Health and Human Services Inspector General maintains a toll-free telephone
number, 800-368-5779, for receiving information concerning fraud, waste or abuse under grants
and cooperative agreements. Such reports are kept confidential, and callers may decline
to give their names if they choose to remain anonymous.

NOTE 11: PAYMENT: Payment under this award will be on the direct payment method. At CDC, recipients are placed on one of the two payment methods.

These are Direct Drawdown or Direct, and Manual Drawdown or Manual. It is preferred that Recipients maintain good standing in all fiscal and programmatic areas, thus, maintaining status on a direct drawdown basis, however, under certain conditions, recipients are placed on manual drawdown.

For those recipients placed on manual drawdown, the CDC GMO will monitor and control all

NOTICE OF COOPERATIVE AGREEMENT	1	DATE ISSUED
AWARD (Continuation Sheet)	AWARD NO.	U64/CCU919440-05

payment advances for your award. Therefore, PMS 270 forms, as well as correspondence related to payments must be forwarded to the attention of your assigned GMS.

If you are authorized <u>direct drawdown</u>, funds will be obtained directly through the Payment Management System (PMS). PMS is administered by the Division of Payment Management, Program Support Center, DHHS. The PMS will forward the following information to you:

- (1) the <u>DHHS Manual for Recipients Financed Under the Payment Management System</u> (PMS)
- (2) the PMS-272 (Status of Federal Cash) forms
- (3) PMS Contact person that is responsible for your account
- (4) Instructions regarding direct deposit and other payment routes.

PMS correspondence, mailed through the U. S. Postal Service, should be addressed as follows:

Division of Payment Management, FMS/PSC/HHS,

P. 0. Box 6021 Rockville, MD 20852.

If a carrier other than the U. S. Postal Service is used, such as United Parcel Service, Federal Express, or other commercial service, the correspondence should be addressed as follows:

Division of Payment Management, FMS/PSC/HHS, Rockwall Building #l, Suite 700, 11400 Rockville Pike, Rockville, MD 20852.

Note 12: AUDIT FILING COMPLIANCE: An organization that expends \$300,000 (\$500,000 for fiscal years ending after December 21, 2003) or more in a year in Federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of OMB Circular A-133, Audit of States, Local Governments, and Non-Profit Organizations. It must be completed and a data collection form, and reporting package shall be submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine months after the end of the audit period. The audit report must be sent to: Federal Audit Clearing House, Bureau of the Census, 1201 East 10<sup>th</sup> Street, Jacksonville, IN 47132. Should you have questions regarding the submission or processing of your Single Audit package, contact the Federal Audit Clearinghouse at:

(301) 763-1551 (800) 253-0696 OR email: govs.fac@census.gov

Note 13: KEY PERSONNEL: In accordance with 45 CFR 92.30 (d)(3). Grantee must obtain prior approval of the awarding agency whenever there are changes in key persons where specified in an application or a grant award.

#### Key Personnel:

Director: Paul Simon, M.D., MPH

Principal Investigator: Amy Wohl, Ph.D.

NOTICE OF COOPERATIVE AGREEMENT	Page - 4 -	DATE ISSUED	
AWARD (Continuation Sheet)	AWARD NO.	U65/CCU919440-05	

# NOTE 14: CDC CONTACT NAMES:

# Grants Management Contact

Roslyn Curington, Grants Management Specialist Centers for Disease Control and Prevention (CDC) Procurement and Grants Office 2920 Brandywine Road E-15 Atlanta, Georgia 30341-4146 Telephone: (770) 488-2767

Fax: (770) 488-2670 or 2671 E-mail: rcurington@cdc.gov

### Programmatic Contact

Paul Weidle, Project Officer Centers for Disease Control and Prevention (CDC) Division of HIV/AIDS Prevention Corporate Square, Bldg. 8, MS E-58 Atlanta, GA 30333

Telephone: 404-639-6155 Fax: 404-639-6127

E-Mail: pweidle@cdc.gov

# COUNTY OF LOS ANGELES - DEPARTMENT OF HEALTH SERVICES HIV EPIDEMIOLOGY PROGRAM

# Intervention Epidemiologic Research Study on HIV/AIDS (DAART) Cooperative Agreement No. U62/CCU919440 Estimated Budget September 30, 2004 - September 29, 2005

1.	COUNTY PERSONNEL	Annual Salary	Monthly Salary	# of Positions	% of Time	# of Mos.	Total
	Principal Investigator Amy Wohl, Ph.D.	\$79,104	\$6,592	1	50%	12	\$39,552
	Co-Investigator Robert La rsen		n/a	1	5%	12	In-Kind
	Research Analyst II Wendy Garland, MPH	51,636	4,303	1	90%	12	46,473
	Epidemiology Analyst Rosa Valencia	49,152	4,096	1	75%	12	36,864
	Total Salaries				220%		122,889
	Employee Benefits @40.0659% Total Salaries & EB						49,236 <b>172,125</b>
II.	Operating Expenses:						
	Office Supplies Mileage/Parking Travel/Training Space/Rent Subtotal Operating						1,000 585 2,000 10,560 14,145
	Total Operating Expenses						\$14,145
III.	Indirect Cost @ 21.7971%						26,786
IV.	Total Budget						\$213,056